

Opinion Regarding the Use of Controlled Substances in Pain Treatment

Legal Authority

This is a Board opinion issued pursuant to the Board's statute, KRS 311.602, to assist licensees in determining what actions would constitute unacceptable conduct under the provisions of KRS 311.595. The Board has decided to publish this opinion because it addresses issues of significant public and medical interest.

This opinion is not a statute or administrative regulation, and does not have the force of law.

The Board has determined that the following principles constitute the standards of acceptable and prevailing medical practice relating to a physician's use of controlled substances in the treatment of chronic, non-malignant pain. If the Board should receive a grievance that a physician has departed from the acceptable and prevailing standards of medical practice, the Board and its Hearing Officer will consider the grievance in light of these standards, the actual patient records and expert testimony specific to the physician's practice.

Introduction

The Kentucky Board of Medical Licensure (KBML) recognizes that principles of quality medical practice dictate that the people of Kentucky have access to appropriate and effective pain relief. The appropriate application of state-of-the-art treatment modalities can serve not only to improve the quality of life for those patients who suffer from pain, but also can reduce the morbidity and costs associated with inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic. Pain management is particularly important for patients who experience pain as a result of terminal illness and can be difficult for patients with chronic non-terminal pain. It is imperative that physicians become knowledgeable about effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result either from physicians' lack of knowledge about pain management or their misunderstanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may

also result in inappropriate or inadequate treatment of the pain patient.

Accordingly, **this Opinion has been developed to clarify the Board's position on pain control, especially as related to the use of controlled substances for non-terminal/non-malignant chronic pain, in order to alleviate physician uncertainty and to encourage better pain management.**

The Board recognizes that controlled substances (including opioid analgesics, benzodiazapines and stimulants) may be essential in the treatment of acute pain and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain should be based on current knowledge and research and includes the use of both pharmacological and non-pharmacological modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that *tolerance* and *physical dependence* are normal consequences of sustained use of opioid analgesics and are not synonymous with *addiction*. *Addiction* refers to both dependence on the use of substances for the drugs' psychic effects and compulsive use of the drug despite consequences.

The KBML is obligated under the laws of the state of Kentucky to protect the public health and safety. The Board recognizes that the inappropriate prescribing of controlled substances may lead to drug diversion and abuse by individuals who seek the drugs for other than legitimate medical use. Physicians must be diligent in preventing the diversion of drugs for illegitimate purposes. The Board believes the adoption of this Opinion will protect legitimate medical uses of controlled substances, while helping to prevent drug diversion and eliminating inappropriate prescribing practices.

Physicians should not fear disciplinary action from the Board for prescribing controlled substances for a legitimate medical purpose and in the usual course of professional practice. The Board will consider the prescribing of controlled substances for pain a legitimate medical purpose, if such prescribing is (1) based on accepted scientific knowledge of pain treatment and (2) if based on sound clinical grounds. All such prescribing must be grounded in clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis if and when brought to the Board's attention. The Board does not take disciplinary action against a physician who fails to adhere strictly to the provisions of this Opinion, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account: (1) whether or not the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis; (2) the patient's individual needs – including improvement in functioning; and (3) a recognition that some types of pain cannot be completely relieved.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than only the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following Opinion is not intended to define complete or best practice, but rather to communicate what the Board considers to be within acceptable boundaries of professional practice when prescribing for recurrent or persistent chronic pain. An Opinion regarding the prescribing for acute pain would be appropriately less stringent but, in principle, the same.

Board Opinion

The Kentucky Board of Medical Licensure has adopted the following Opinion for evaluating the use of controlled substances for control of **recurrent or chronic pain**.

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. A Family History should be documented with particular reference to any history of first degree relative with chemical dependence problems. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of any substance abuse. The medical record also should document the presence of one or more recognized medical indication(s) for the use of a controlled substance.

By definition, pain is a *subjective* statement of a patient's perception of actual or potential tissue damage. The distinction between pain and suffering should be established. A patient may suffer due to pain, but may have other reasons for suffering as well. The assessment of a patient's overall condition should be made at the initial evaluation and thereafter. It is the goal of the physician to assist in the relief of suffering no matter the cause. Financial, emotional, mental, physical, and spiritual factors may contribute to the patient's suffering. Relief of the underlying reasons for suffering as well as the pain will lead to optimal treatment and utilization of controlled substances.

Before beginning a regimen of controlled drugs, the physician must determine, through actual clinical trial or through patient records and history that non-addictive medication regimens have been inadequate or are unacceptable for solid clinical reasons. Speaking with the patient's significant other or conducting a family conference can be helpful if there is any doubt regarding the patient's integrity. Utilizing the Kentucky All Schedule Prescription Electronic Reporting [i.e., KASPER Report] initially can also aid in documenting the patient's history of drug utilization.

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations, consultations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consents and Treatment Agreements

The physician should discuss the risks and benefits of the use of controlled substances with the patient or his/her surrogate, including the risk of tolerance and drug dependence. If the patient is determined to be at *high risk* for medication abuse or have a history of substance abuse, the physician may employ the use of a written *agreement* between physician and patient outlining patient responsibilities, including:

- One prescribing doctor and one designated pharmacy.
- Urine/serum drug screening when request.
- No early refills and no medications called in. If medications are lost or stolen, then a police report could be required before considering additional prescriptions.
- The reasons for which drug therapy may be discontinued such as violation of a documented doctor-patient *agreement*.

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as reduction in patient's pain intensity and improved physical and/or psychosocial function (i.e., ability to work), need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans. Periodic requests for a **KASPER Report** could be utilized.

5. Consultation

The physician should be willing to refer the patient as clinically indicated for additional evaluation and in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a coexisting psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

6. Medical Records

The physician should keep accurate and complete records to include:

- The medical history and physical examination;
- Diagnostic, therapeutic, and laboratory results;
- Evaluations and consultations;

- Treatment objectives;
- Discussion of risk, benefits, and limitations of treatments;
- Treatments;
- Medications (including date, type, dosage, and quantity prescribed);
- Instructions and agreements;
- Periodic reviews; and
- Records should remain current and be maintained in an accessible manner and readily available for review.

Initial or periodic **KASPER Report(s)** should *not* be part of the patient's records and should not be released to the patient or a third party.

7. Compliance With Controlled Substances Laws and Regulations

To prescribe, dispense, or administer controlled substances, the physician must have an active license in the state and comply with applicable federal and state regulations.

Physicians should studiously **avoid** prescribing scheduled drugs for themselves, immediate family, or staff in accordance with the American Medical Association's Code of Medical Ethics and the KRS Medical Practice Act.

Conclusion: By publishing this Opinion, the KBML wishes to encourage physicians to utilize adequate medications to treat their patients with serious pain complaints without undue fear of legal or licensure repercussions. Concurrently the Board strives to prevent, as much as possible, drug diversion and inappropriate prescribing practices.

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